AORN
Association of periOperative Registered Nurses
2170 South Parker Road, Suite 300 • Denver, CO 80231-5711 • (303) 755-6300 or (303) 755-6304 • http://www.aorn.org/

October 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0313, RIN 0910-AB74

To Whom It May Concern:

AORN (the Association of periOperative Registered Nurses) represents nearly 43,000 RNs working in hospital operating rooms and ambulatory surgery centers across the country. We respectfully submit our comments to the proposed rule change for reclassification of Surgeon's and Patient Examination Gloves, as noticed in the Federal Register on Friday, July 30, 1999 (Vol. 64, No. 146, beginning at page 41710.) These comments are specifically in response to VI. Specific Request for Comments on page 41716.

1. Like the FDA, AORN would prefer a one-year effective date. However, AORN would want consideration given to the timing of the effect of a new rule, if the one-year effective date is certain to create a shortage of medical gloves. What measures has the FDA taken to ensure that the estimates given by industry of the required time needed to make the necessary changes are true estimates? Has any investigation been done other than to ask industry for their estimated time line? Unless it can be demonstrated that a serious glove shortage "would" result, AORN favors a one-year effective date.

2. Since the rationale for the rule change contends that some gloves are presently at a powder level considerably less than the proposed 120 mg, AORN would support dropping the requirement to a lower figure (e.g., in the 90-100 mg range).

3. AORN cannot speak to the feasibility of additional labeling of the primary ingredients in the glove powder used. However, AORN contends that additional labeling is desirable.

4. AORN favors the labeling requirements for each product to be labeled appropriately according to the presence of natural latex rubber. Further, AORN supports the requirement for expiration dating based on product degradation as shown by appropriate testing. AORN opposes accepting or recommending any amount of a substance which the label identifies as absent in the product.

5. With the increased incidence of various types of allergic reactions to powered gloves, it would be prudent to move to a powder-free environment. Use of powder-free gloves will reduce the number of airborne protein particles that may precipitate allergic reactions among patients and personnel. However, cost factors may prohibit some providers from moving to a totally powder-free environment. AORN, therefore, opposes a requirement for powder-free gloves to be used exclusively, but supports a recommendation for that practice.

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6. As noted in item number 5

7. No comment

8. AORN commends the FDA in its effort to reduce adverse public health effects from allergic reactions and foreign body reactions and is interested in any methodology that will achieve this objective.

9. AORN strongly believes that whatever levels ultimately are selected to be included in the document, those levels should be required and not just recommended. Recommendations do not drive compliance, as do requirements.

10. AORN supports determination of shelf life based on documented studies of product degradation and sterility maintenance.

11. AORN opposes the requirement for use of special air-handling systems where glove powder levels exceed the defined maximum level. Such systems are costly to install and even more costly to maintain. The on-going cost of the air-handling system and its maintenance would outweigh the cost of gloves with a lesser powder content.

12. AORN opposes a provision permitting affected persons to request exemptions from the labeling requirements in the document.

Thank you for allowing AORN to comment on the proposed regulations. If you have additional questions for our association, please do not hesitate to contact Dorothy Fogg at the Denver office.

Sincerely yours,

Pat Palmer

Patricia Niessner Palmer, RN, ~~MS,~~ MNM, CAE
Executive Director

PNP/clr

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